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FEB 2 2 2006

K060283

Bonutti Research, Inc. – Modification to TranSet™ System
Special 510(k)
February 1, 2006

510(k) SUMMARY

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

Contact Person: Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA
Bonutti Research, Inc.,
P.O. Box 1367, Effingham, Illinois 62401
Phone: (217) 342-3412, ext. 321
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Date Prepared: February 1, 2006

Proprietary Name: TranSet™ System

Common Name: Fixation Device

Classification Name: Fastener, Fixation, Nondegradable, Soft Tissue. Smooth or threaded metallic bone fixation fastener.

Device Description: The TranSet™ System intended use is in the dynamic stabilization and linear fixation of bone, tissue, ligament, and tendon fragments in surgical procedures. The system consists of a cannulated drill, a lead button or anchor, a flexible material that runs across a repair site, a metallic crimp, and a manual hand held crimping instrument. The flexible material is tensioned and secured with a metallic crimp by the manual hand held instrument allowing a compressive load to be applied across the repair site. This compression and holding together of the bone, tissue, ligament, and tendon fragments further promotes healing at the repair site. Lead buttons or anchors with a corresponding flexible material are provided sterile for single patient use. Cannulated drills for delivery of the implant materials are single patient use. The reusable crimping instrument and a sterilization tray for autoclaving complete the system.

Indications for Use: The TranSet™ System are fixation devices indicated in bone, tissue, ligament, and tendon repair. The system allows for dynamic stabilization and linear fixation of bone, tissue, ligament, and tendon fragments in surgical procedures. The system can also be used as fixation posts for distributing suture tension over areas of bone, tissue, ligament, and tendon repair. The compression and holding together of bone, tissue, ligament, and tendon fragments of the system further promotes healing at the repair site. The system consists of single patient use metallic crimping devices that secure the following flexible materials running across a repair site:

- Up to USP Size No. 2 Suture,
- Up to USP Size No. 2 High Tensile Suture,
- Metallic Cable, and
- Metallic Wire.

Predicate Device(s): The modified TranSet™ System is similar in design and intended use to the existing Multitak SS Button system and to stainless steel beaded cable systems and Steinmann pins commonly used in bone fracture repairs.

Predicate Comparison: Design verification testing identified and conducted as part of the risk analysis assessment compared the mechanical strengths and failure modes of the modified TranSet™ System to predicate devices. Results demonstrated that the modified TranSet™ System is statistically equivalent to predicate devices.

Submitted by:

Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2006

Mr. Patrick Balsmann
Director, Regulatory/Clinical Affairs & QA
Bonutti Research, Inc.
PO Box 1367
Effingham, Illinois 62401

Re: K060283
Trade/Device Name: TranSet™ System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: February 1, 2006
Received: February 8, 2006

Dear Mr. Balsmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: TranSet™ System

Indications For Use: The TranSet™ System are fixation devices indicated in bone, tissue, ligament, and tendon repair. The system allows for dynamic stabilization and linear fixation of bone, tissue, ligament, and tendon fragments in surgical procedures. The system can also be used as fixation posts for distributing suture tension over areas of bone, tissue, ligament, and tendon repair. The compression and holding together of bone, tissue, ligament, and tendon fragments of the system further promotes healing at the repair site. The system consists of single patient use metallic crimping devices that secure the following flexible materials running across a repair site:

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- Up to USP Size No. 2 High Tensile Suture,
- Metallic Cable, and
- Metallic Wire.

Prescription Use__X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060283